Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Wormit Plus 12.5mg/125 mg Chewable Tablets for Dogs

Date Created: December 2025

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Wormit Plus 12.5mg/125 mg Chewable Tablets for Dogs
Applicant	C&H Generics Ltd, c/o Michael McEvoy and Co, Seville House, New Dock Street, Galway, Ireland
Active substance	Milbemycin Oxime (A3 and A4) Praziquantel
ATC Vetcode	QP54AB51
Target species	Dogs
Indication for use	For dogs with, or at risk from mixed infections of cestodes, gastrointestinal nematodes, eyeworm, lungworms and/or heartworm. This veterinary medicinal product is only indicated when use against cestodes and nematodes or prevention of heartworm disease/ angiostrongylosis is indicated at the same time. **Cestodes:** • Treatment of tapeworms: *Dipylidium caninum*, *Taenia* spp., *Echinococcus* spp., *Mesocestoides* spp. **Gastrointestinal Nematodes:** Treatment of: • Hookworm: *Ancylostoma caninum* • Roundworms: *Toxocara canis, Toxascaris leonina* • Whipworm: *Trichuris vulpis* **Eyeworm:** • Treatment of *Thelazia callipaeda* (see specific treatment schedule under section 3.9 **"**Administration routes and dosage**"**).

	Lungworms: Treatment of: • *Angiostrongylus vasorum* (Reduction of the level of infection by immature adult (L5) and adult parasite stages; see specific treatment and prevention disease schedules under section 3.9 **"**Administration routes and dosage**"**), • *Crenosoma vulpis* (Reduction of the level of infection). **Heartworm** Prevention of heartworm disease (*Dirofilaria immitis*) if concomitant treatment against cestodes is indicated.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended.
Date of conclusion of the procedure	23/10/2025

I. SCIENTIFIC OVERVIEW

The product was submitted for a generic application for authorisations in Great Britain (GB) and Northern Ireland, in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended. The reference product in GB is Milbemax 12.5 mg/125 mg Chewable Tablets for Dogs (Vm: 00879/5031) marketed by Elanco Europe Ltd, authorised in the UK since 2010. The reference product for NI is Milbemax 12.5 mg/125 mg Chewable Tablets for Dogs (VPA 22020/008/004) marketed by Elanco Europe Ltd, authorised in IE since 2016. The applicant claimed that the GB and NI reference products are identical and provided a bioequivalence study.

Wormit Plus 12.5mg/125 mg Chewable Tablets for Dogs contain 12.5 mg milbemycin oxime and 125 mg praziquantel. The product is indicated for dogs with, or at risk from mixed infections of cestodes, gastrointestinal nematodes, eyeworm, lungworms and/or heartworm.

The dosage is 0.5 mg milbemycin oxime and 5 mg praziquantel per kg, administered as a single dose. The product should be administered with or after some food.

The distribution category in GB and NI is POM-V, the same as the reference products.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released on the market. It has been shown that the product can be safely used in the target species, any reactions observed are indicated in the SPC[1]. The product is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy[2] of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

[1] SPC – Summary of Product Characteristics.
[2] Efficacy – The production of a desired or intended result.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains milbemycin oxime and praziquantel and the excipients propylene glycol (E 1520), brown iron oxide (E 172), butylhydroxyanisole (E 320), propyl gallate (E 310), glycerol (E 422), pre-gelatinised pea starch, chicken flavour, confectioner's sugar, purified water, sodium chloride and citric acid monohydrate.

The container/closure system consists of blister packs made up of a cold form laminate of OPA/ALU/PVC of thickness 25µm/47µm/60µm with a 20µm hard tempered aluminium foil, packaged in a cardboard box. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative are justified.

The product is an established pharmaceutical form, and its development is adequately described in accordance with the relevant regulatory guidelines.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant regulatory guidelines.

II.C. Control of Starting Materials

The active substances are milbemycin oxime and praziquantel, established active substances described in the European Pharmacopoeia, and are supplied in accordance with appropriate Certificates of Suitability (CEPs). The active substances are manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

The excipients described in pharmacopoeia are tested for compliance with the requirements of their respective monographs. The grade of pre-gelatinised starch used is not described in the pharmacopoeia and the applicant has provided an appropriate justification for using the non-pharmacopoeial material.

Declarations of compliance with EU Regulations 10/2011 and 1935/2004/EC for materials in contact with food have been provided by the suppliers of packaging materials.

II.C.4. Substances of Biological Origin

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form.

The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the production sites have been provided demonstrating compliance with the specification. Control tests on the finished product are those appropriate for the pharmaceutical form.

II.F. Stability

Stability data on the active substances have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

The shelf life of the product as packaged for sale is 18 months. The product should be used immediately after first opening the immediate packaging.

The product should not be stored above 25°C.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

Due to the legal basis of the application, no new pharmacological or toxicological studies were submitted.

Warnings and precautions as listed on the product literature are comparable to those of the reference products and are adequate to ensure safety of the product to users/the environment.

III.A Safety Documentation

Pharmacological Studies

As is appropriate for the legal basis of the application, no new pharmacological studies were submitted.

The pharmacodynamics and pharmacokinetics of the active ingredients are the same as the reference products.

Milbemycin oxime belongs to the group of macrocyclic lactones and is active against mites, against larval and adult stages of nematodes as well as against larvae of *Dirofilaria immitis*.

The activity of milbemycin is related to its action on invertebrate neurotransmission. It increases nematode and insect membrane permeability to chloride ions which leads to hyperpolarisation of the neuromuscular membrane and flaccid paralysis and death of the parasite.

After oral administration of milbemycin oxime in dogs, peak plasma levels occur at about 2-4 hours and bioavailability is about 80%. In the rat, metabolism appears to be complete although slow, since unchanged milbemycin oxime has not been found in urine or faeces.

Praziquantel is an acylated pyrazino-isoquinoline derivative, active against cestodes and trematodes. It modifies the permeability for calcium in the membranes of the parasite, inducing an imbalance in the membrane structures, resulting in easier expulsion from the gastrointestinal tract or death of the parasite.

After oral administration of praziquantel in the dog, peak serum levels of parent are rapidly attained (T_{max} approximately 0.5-4 hours) and decline quickly ($t_{1/2}$ approximately 1.5 hours). There is a substantial hepatic first-pass effect and plasma binding is about 80%. Excretion is fast and the principal route of elimination is renal.

Toxicological Studies

As is appropriate for the legal basis of the application, no new toxicological studies were submitted.

User Safety

A user risk assessment was provided in compliance with the relevant guideline which shows that no unacceptable risk for the user is expected if the products are used as directed.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore, the following applicant's user recommendations are appropriate:

- This veterinary medicinal product may be harmful when ingested, particularly for children. To avoid accidental ingestion, the veterinary medicinal product should be stored out of sight and reach of children.
- In case of accidental ingestion of the tablets, particularly by a child, seek medical advice immediately and show the package leaflet or the label to the physician.
- This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to the active substances or to the excipients, butylhydroxyanisole (E320) and propyl gallate (E310), should avoid contact with the veterinary medicinal product. If contact occurs, wash hands and seek medical advice in case of hypersensitivity reactions.
- Wash hands after use.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

The product will only be used in non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required. No unacceptable risk to the environment is expected if the products are used as directed.

IV. CLINICAL DOCUMENTATION

IV.II. Clinical Documentation

The applicant submitted an *in vivo* bioequivalence study conducted with 24 clinically healthy, Beagle dogs using the European Milbemax 12.5 mg/125 mg chewable tablets for dogs (VPA 22020/008/004) as the reference item.

The study was a randomised, single-dose, two-period, two-sequence, cross-over design, with a wash out period of 28 days. Appropriate blood sampling schedules were used and results showed that bioequivalence with the reference product could be accepted.

Additionally, the applicant provided a literature review regarding the current status of milbemycin and praziquantel resistance in the target parasites.

Due to the legal category of the application and as bioequivalence with the reference product was accepted, further efficacy studies were not required. The efficacy claims, dosing regimens, and pharmacology for the product are equivalent to those of the reference product.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics the benefit/risk profile of the product is favourable.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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